

Drug Administration that his drugs were violative of the Act through establishment inspections, by letter, by a hearing and through two seizures of the article of drug designated as "Herb Tea" which seizures were terminated by default; and, that despite such warnings, defendant continued to violate the Act as specified above.

It was alleged further that if defendant was forced by an injunction to refrain from using the present labeling on the articles of drugs distributed by him, the said defendant would not discontinue such distribution but would, unless enjoined, continue to distribute in interstate commerce, and while held for sale after shipment in interstate commerce, such articles of drugs without labeling, or through collateral media outside of labeling. In such case, the articles of drugs would be misbranded within the meaning of Section 502(f)(1) of the Act in that their labeling would fail to bear adequate directions for use for the purposes for which they were intended.

DISPOSITION: Following a conference prior to a hearing on the motion for preliminary injunction on 5-26-58, the court ordered (1) that the defendant submit proposed labels and quantitative formula to the Government by mail not later than 6-2-58, and (2) that the Government thereafter comment on the proposed labels and proceed with its motion for preliminary injunction if the labels were objectionable. Subsequently, on 6-29-59, the defendant having relabeled the products, and the United States Attorney having agreed, the case was ordered dismissed by the court.

6007. Pre-Creatine (betaine anhydrous). (F.D.C. No. 43129. S. Nos. 38-991/2 P, 38-993/7 P.)

QUANTITY: 1 drum, containing 15 lbs. Pre-Creatine capsules, 108 8-oz. btls. of Pre-Creatine granules, 58 100-capsule btls. and 21 50-capsule btls. of *Pre-Creatine*, at Palo Alto, Calif.

SHIPPED: During 1958, the Polychemical Laboratories, Inc., shipped from New York, N.Y., to a manufacturer at San Jose, Calif., quantities of betaine anhydrous.

LABEL IN PART: (Drum) "Pre-Creatine Caps."; (btl.) "Granules Pre-Creatine, Lemon-Orange Flavor * * * Effervescent Recommended Dosage 1 Tablespoonful * * * Each Tablespoonful Contains Approx: betaine anhydrous 2 grams glycocyamine 0.5 grams," "Capsules Pre-Creatine * * * Recommended Dosage 2 capsules t.i.d. Each Capsule Contains betaine anhydrous 400 mg. glycocyamine 100 mg."

RESULTS OF INVESTIGATION: The California manufacturer used the betaine anhydrous in the manufacture of the *Pre-Creatine* and shipped in bulk the drug so manufactured to a dealer at Palo Alto, Calif. The drugs in the bottles labeled as described above were repacked by the dealer from the bulk stock shipped to him from the California manufacturer.

LIBELED: 5-6-59, N. Dist. Calif.

CHARGE: 502(f)(1)—the labeling of the betaine anhydrous, when shipped in interstate commerce, failed to bear adequate directions for use and such article was not entitled to exemption from the requirement that its labeling bear adequate directions.

DISPOSITION: 9-30-59. Default—destruction.